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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/626,366	07/24/2000	Cathy Ilyse Hess	D4857-00006	7385

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EXAMINER	
FRENEL, VANEL	
ART UNIT	**PAPER NUMBER**
3626	

DATE MAILED: 11/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/626,366	HESS, CATHY ILYSE	
	Examiner	Art Unit	
	Vanel Frenel	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Recent Statutory Changes to 35 U.S.C. § 102(e)

On November 2, 2002, President Bush signed the 21st Century Department of Justice Appropriations Authorization Act (H.R. 2215) (Pub. L. 107-273, 116 Stat. 1758 (2002)), which further amended 35 U.S.C. § 102(e), as revised by the American Inventors Protection Act of 1999 (AIPA) (Pub. L. 106-113, 113 Stat. 1501 (1999)). The revised provisions in 35 U.S.C. § 102(e) are completely retroactive and effective immediately for all applications being examined or patents being reexamined. Until all of the Office's automated systems are updated to reflect the revised statute, citation to the revised statute in Office actions is provided by this attachment. This attachment also substitutes for any citation of the text of 35 U.S.C. § 102(e), if made, in the attached Office action.

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 102 in view of the AIPA and H.R. 2215 that forms the basis for the rejections under this section made in the attached Office action:

> **A person shall be entitled to a patent unless –**
>
> **(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for** purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

35 U.S.C. § 102(e), as revised by the AIPA and H.R. 2215, applies to all qualifying references, except when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. For such patents, the prior art date is determined under 35 U.S.C. § 102(e) as it existed prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. § 102(e)).

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 102 prior to the amendment by the AIPA that forms the basis for the rejections under this section made in the attached Office action:

> **A person shall be entitled to a patent unless –**
>
> **(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.**

For more information on revised 35 U.S.C. § 102(e) visit the USPTO website at www.uspto.gov or call the Office of Patent Legal Administration at (703) 305-1622.

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the application filed July 2000.Claims 1-16 are pending.

Claim Rejections - 35 USC § 112 2nd Paragraph

2. Claim 2 is rejected under 35 U.S.C.112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claims 2-3 recite the limitations "the use of a risk assessment tool comprising a rating scale to objectively characterize the condition of said patient's skin and wound" and "with the formation of a selected malady". There are insufficient antecedent basis for these limitations in the claims. It is unclear as to what Applicant is referring to "the use of a risk assessment tool comprising a rating scale to objectively characterize the condition of said patient's skin and wound" and "with the formation of a selected malady". Applicant is requested to amend the claims to recite proper antecedent basis in the next communication.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1 and 9 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Under the guidance of recent law, the requirements of 35 U.S.C. 101 are met when the practical application of the abstract idea produces a useful, concrete, and tangible result (State Street Bank & Trust Co. vs. Signature Financial Group, Inc., 47 USPQ2d 1596,1601-02 (Fed.Cir.1998)). However, claims 1 and 9 as presently recited, do not appear to have a concrete result.

The claims presently recited do not fall within the technological arts as no specific technology (e.g., processor, computer) is expressly recited in the body of the claims. In re Toma (CCPA) 197 USPQ 852 (1978). Further, inventions directed merely to a human making mental computations and manually tabulating results on paper are not tied to any technological art or environment. Ex parte Bowman (BPAI) 61 USPQ2d 1669 (2001).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dang (6,370,511) in view of Hennessy et al (6,277,071).

(A) As per claim 1, Dang discloses a method for assessing deviations from a preselected medical treatment that has been indicated by appropriate diagnosis from a clinician, comprising the steps of:

(A) (A) gathering patient care data and diagnosing a malady (Col.9, lines 21-61);

(B) storing said patient care data in a data storage means (Col.12, lines 40-67;

(C) identifying an appropriate clinical pathway to follow in treating said **diagnosed malady (Col.12, lines 27-67 to Col.13, line 27);**

(D) implementing said identified clinical pathway and recording clinical actions taken by a clinician in said data storage means (Col.12, lines 27-67).

Dang does not explicitly disclose monitoring said recorded clinical actions taken by said clinician to determine variations from said identified clinical pathway; and alerting said clinician of a variance from said identified clinical pathway.

However, these features are known in the art, as evidenced by Hennessy. In particular, Hennessy suggests monitoring said recorded clinical actions taken by said clinician to determine variations from said identified clinical pathway; and alerting said clinician of a variance from said identified clinical pathway (See Hennessy Col.5, lines 30-67 to Col.6, line 51; Col.9, lines 64-67 to Col.10, line 56).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the features of Hennessy within the system of Dang with the motivation of providing a processor which separates the patient entries designated by the user according to a test threshold stored in said guideline. The test thresholds represent known parameters associated with the chronic disease, such as blood glucose, lipids, liver enzyme and microalbumin for the disease of diabetes. If the test threshold value derived from the guideline is exceeded, an alert sequence is activated, in which the patient is categorized as a high risk patient, the physician is notified, the patient is notified, the health care provider is notified, and the patient's treatment is altered to treat the high risk patient (See Hennessy Col.4, lines 26-37).

(B) As per claim 2, Hennessy discloses a method according wherein said gathering of said patient care data includes the use of a risk assessment tool comprising a rating scale to objectively characterize the condition of said patient's skin and wound (See Hennessy Fig.20; Col.10, lines 29-60).

The motivation for combining the respective teachings of Dang and Hennessy are as discussed above in the rejection of claim 1, and incorporated herein.

(C) As per claim 3, Hennessy discloses a method according wherein said rating scales factors most closely associated with the formation of a selected malady (Col.2, lines 36-67 to Col.3, line 8).

The motivation for combining the respective teachings of Dang and Hennessy are as discussed above in the rejection of claim 1, and incorporated herein.

(D) As per claim 4, Hennessy discloses a method wherein said factors are associated with parameters that are identified and assessed by said clinician, and a rating number assigned to each of said parameters that corresponds to said clinician's objective assessment of a wound/skin condition (See Hennessy Fig.20; Col.10, lines 1-60).

The motivation for combining the respective teachings of Dang and Hennessy are as discussed above in the rejection of claim 1, and incorporated herein.

(E) As per claim 5, Hennessy discloses a method wherein said a finite numerical score is selected from a preselected range and assigned to each of said parameters (Col. 9, lines 29-63).

The motivation for combining the respective teachings of Dang and Hennessy are as discussed above in the rejection of claim 1, and incorporated herein.

(F) As per claim 6, Hennessy discloses a method wherein a numerical score at or above a preselected value is indicative of a high risk for development of said malady (Col.9, lines 64-67 to Col.10, line 23).

The motivation for combining the respective teachings of Dang and Hennessy are as discussed above in the rejection of claim 1, and incorporated herein.

(G) As per claim 7, Hennessy discloses a method wherein said parameters, along with their assigned scores, are stored at a known, searchable, and retrievable location in said data storage means (Col.9, lines 29-63).

The motivation for combining the respective teachings of Dang and Hennessy are as discussed above in the rejection of claim 1, and incorporated herein.

(H) As per claim 8, Hennessy discloses a method wherein said monitoring includes reviewing each of said parameters, and identifying a most likely course of intervention to be followed by said clinician (Col.11, lines 1-45).

The motivation for combining the respective teachings of Dang and Hennessy are as discussed above in the rejection of claim 1, and incorporated herein.

(I) As per claim 9, Dang discloses a method for assessing deviations from a preselected medical treatment that has been indicated by appropriate diagnosis from a clinician, comprising the steps of:

(A) gathering patient care data and diagnosing a malady (Col.9, lines 21-61);

(B) storing said patient care data in a data storage means of a general purpose computer (Col.12, lines 40-67);

(C) identifying an appropriate clinical pathway to follow in treating said diagnosed malady (**Col.12, lines 27-67 to Col.13, line 27);**

(D) implementing said identified clinical pathway and recording clinical actions taken by a clinician in said data storage means (Col.12, lines 27-67).

Dang does not explicitly disclose monitoring said recorded clinical actions taken by said clinician to determine variations from said identified clinical pathway; and alerting said clinician of a variance from said identified clinical pathway.

However, these features are known in the art, as evidenced by Hennessy. In particular, Hennessy suggests monitoring said recorded clinical actions taken by said clinician to determine variations from said identified clinical pathway; and alerting said clinician of a variance from said identified clinical pathway

(See Hennessy Col.5, lines 30-67 to Col.6, line 51; Col.9, lines 64-67 to Col.10, line 56).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the features of Hennessy within the system of Dang with the motivation of providing a processor which separates the patient entries designated by the user according to a test threshold stored in said guideline. The test thresholds represent known parameters associated with the chronic disease, such as blood glucose, lipids, liver enzyme and microalbumin for the disease of diabetes. If the test threshold value derived from the guideline is exceeded, an alert sequence is activated, in which the patient is categorized as a high risk patient, the physician is notified, the patient is notified, the health care provider is notified, and the patient's treatment is altered to treat the high risk patient (See Hennessy Col.4, lines 26-37).

(J) As per claim 10, Hennessy discloses a method wherein said gathering of said patient care data includes observing and recording a patient's vital signs (Col.7, lines 26-51).

The motivation for combining the respective teachings of Dang and Hennessy are as discussed above in the rejection of claim 9, and incorporated herein.

(K) As per claim 11, Hennessy discloses a method wherein said recorded vital signs are each compared to a preselected value for said vital sign and monitored for deviations that are indicative of a high risk for development of a skin malady (See Hennessy Fig.20; Col.10, lines 1-60).

The motivation for combining the respective teachings of Dang and Hennessy are as discussed above in the rejection of claim 9, and incorporated herein.

(L) As per claim 12, Hennessy discloses a method wherein said implementing said identified clinical pathway and recording clinical actions taken by said clinician includes implementing a skin and wound care regimen (Col.2, lines 1-35; Col.6, lines 30-67).

The motivation for combining the respective teachings of Dang and Hennessy are as discussed above in the rejection of claim 9, and incorporated herein.

(M) As per claim 13, Hennessy discloses a method wherein said skin and wound care regimen are monitored for deviations that are indicative of a high risk for deterioration of said skin and wound (Col.6, lines 12-67).

The motivation for combining the respective teachings of Dang and Hennessy are as discussed above in the rejection of claim 9, and incorporated herein.

(N) As per claim 14, Hennessy discloses a method wherein said regimen comprises selection and application of dressings to a wound (See Hennessy Fig.20; Col.6, lines 30- 67).

The motivation for combining the respective teachings of Dang and Hennessy are as discussed above in the rejection of claim 9, and incorporated herein.

(O) Claim 15 differs from claims 1 and 9 by reciting a method for assessing deviations from a preselected medical treatment that has been indicated by appropriate diagnosis from a clinician, comprising the steps of:

(A) gathering patient care data according to a predetermined regimen for diagnosing a malady of the skin;

(B) storing said patient care data in a data storage means of a general purpose computer.

As per this limitation,it is noted that Dang discloses (C) identifying an appropriate clinical pathway from a plurality of pathways for treating said diagnosed malady (**Col.12, lines 27-67 to Col.13, line 27);**

(D) implementing said identified clinical pathway via clinical actions taken by a clinician (Col.12, lines 27-67) and Hennessy discloses monitoring said clinical actions taken by said clinician to determine variations from said identified clinical pathway; and alerting said clinician of a variance from said

identified clinical pathway (See Hennessy Col.5, lines 30-67 to Col.6, line 51; Col.9, lines 64-67 to Col.10, line 56).

Thus, it is readily apparent that these prior art systems utilize a predetermined regimen to perform their specified function.

The remainder of claim 16 is rejected for the same reason given above for claims 1 and 9, and incorporated herein.

(P) As per claim 16, Hennessy discloses a method wherein said regimen comprises answering a questionnaire that quantifies a patient's satisfaction with his/her health status (See Hennessy Col.2, lines 8-35).

The motivation for combining the respective teachings of Dang and Hennessy are as discussed above in the rejection of claim 9, and incorporated herein.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied art teaches three step wound treatment method and dressing therefor (4,813,942), system and method for managing patient medical records (5,772,585), medical system and associated method for automatic treatment (5,544,651) and skin patch for use in contact immunotherapy (5,846,559).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vanel Frenel whose telephone number is 703-305-4952. The examiner can normally be reached on 6:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 703-305-9643. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-7687 for regular communications and 703-305-7687 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1113.

V.F
V.F
November 7, 2002

JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3600